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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/016,061	01/30/1998	WILLIAM D. HUSE	P-IX2965	6507

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	31

DATE MAILED: 06/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/016061	Applicant(s) HUSE
	Examiner GAMBEL	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☑ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) _____ is/are pending in the application. 56-128

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) _____ is/are rejected. 56-128

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☑ The drawing(s) filed on 10/15/01 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☑ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission, filed 3/25/02 (Paper No. 28), has been entered.

Applicant's amendment, filed 10/15/01 (Paper No. 24), has been entered.

It is noted in an Interview with applicant's representative Deborah Cadena on 6/14/02 that applicant's request for reconsideration of the previously filed submission, filed 10/15/01 (Paper No. 24), in the Request for Continued Examination (RCE) was intended to be a formal request of entry of the previously unentered amendment.

Claims 56, 60-65, 67,69, 71, 73, 74, 77, 80, 82, 84, 86, 88, 90, 92-96 have been amended.
Claims 105-128 have been added.

Claims 56-128 are pending

Claims 1-55 have been canceled have been canceled previously.

As indicated previously and in the interest of compact prosecution, all of the SEQ ID NOS: have been searched in the instant application.

Claims 98-104 have been withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to a nonelected invention.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Office Action will be in response to applicant's arguments, filed 10/15/01 (Paper No. 24).
The rejections of record can be found in the previous Office Action (Paper Nos. 16, 21, 26).

3. Formal drawings, filed 10/15/01, comply with 37 CFR 1.84.

4. The Abstract of the Disclosure is objected to because it exceeds 150 words. See MPEP 608.01(b).

5. Upon reconsideration of applicant's arguments, filed 10/15/01 (Paper No. 24), the previous rejection under 35 U.S.C. § 112, first paragraph, written description / new matter has been withdrawn given the written support of "one or more CDR's having" in the disclosure as filed, particularly in the original claims.

6. Given the disclosure including the patented claims of U.S. Patent No. 5,753,230 concerning the deposit of the LM609 antibody produced by ATCC HB9537, the previous rejection under 35 USC 112, first paragraph, concerning the deposit of biological materials with respect to the LM609 antibody has been withdrawn.

However, the following is noted.

Applicant's arguments, filed 10/15/01 (Paper No. 24) have been fully considered but are not found convincing essentially for the reasons set forth previously in Paper Nos. 16/21.

Applicant's reliance on the nucleotide and amino acid sequences of the LM609 variable regions is acknowledged.

As pointed out previously, it was noted that if the claimed and disclosed amino acid sequences or nucleic acid sequences set forth in the instant application encode the entire LM609 antibody, then a deposit for said LM609 antibody (hybridoma) is not required. The sequence of an entire immunoglobulin satisfies the biological deposit of said immunoglobulin.

Therefore, applicant's reliance on the variable regions of LM609 does not satisfy the enablement or deposit requirement for biological materials; given that these sequences do not provide for the entire structure of the LM609 immunoglobulin.

7. Claims 80-96 and 109 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "antibodies and functional fragments thereof that bind $\alpha v\beta 3$, does not reasonably provide enablement for any antibody and functional fragment comprising the claimed CDRs in the absence of a clearly defined specificity The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention commensurate in scope with these claims.

The antigen binding properties of a given antibody are principally encoded within the primary and tertiary structure of hypervariable or complementarity determining regions (CDRs) as well as varying in sequence the lengths and conformations of these loops differ from one antibody to the next. It has been known that for each antibody; the antigen binding properties are etched into the tertiary architecture of the combining site, antibody structure itself guides the selection by via affinity in the screening assays, not based upon the primary amino acid sequence alone. There is high stereochemical complementarity between the surfaces of the bound antigen and the antibody combining site.

In the absence of a well defined antigen specificity for the claimed antibody and given the well known polymorphism of immunoglobulins / antibodies; it would not have been predictable that the skilled artisan could have used the claimed antibodies comprising one or more CDRs commensurate in scope with the claimed invention. There is insufficient guidance and direction for a skilled artisan to use antibodies other than those screened for and specific for αvβ3. It would have been undue experimentation to derive the vast repertoire of antibodies encompassed by the claimed invention. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The specification does not describe nor enable any antibody other than those specific for αvβ3.

8. Claims 56-85 and 105-107 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 56-85 and 105-107 are indefinite in the in the recitation of ""enhanced LM609 grafted antibody" because this phrase is relative in nature, which renders the claim indefinite. For example, pages 16-17, overlapping paragraph of the instant specification discloses that the functional characteristic of the antibody has been altered or augmented compared to a reference antibody, which can include both higher or lower affinity. Therefore, the claimed "enhanced LM609 antibody" can have contrasting properties and still be considered enhanced with respect to the referenced LM609 antibody. Further, the terms are not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention

Applicant's arguments, filed 10/15/01 (Paper No. 24), have been fully considered but are not found convincing essentially for the reasons set forth previously in Paper Nos. 16/21/26.

Applicant's arguments, relying on pages 16-17 of the instant specification, and the examiner's rebuttal are essentially the same of record.

The claims now recite certain functional properties such as "having αvβ3 binding activity, αvβ3-inhibitory activity", wherein the αvβ3 binding affinity of said enhanced LM609 grafted antibody is maintained.

Applicant argues that the term "enhanced" is one in which a functional characteristic of the antibody has been altered or augmented compared to a reference antibody so that the antibody exhibits a desirable property or activity (page 16, line 30, to page 17, line 14).

Although the claimed recitation indicates that the binding affinity of the enhanced LM609 antibody is maintained relative to the parental LM609 grafted antibody, the exemplary enhanced activity includes higher or lower affinity, increased or decreased association or dissociation rates or increased stability compared to a reference antibody.

In contrast to applicant's assertions and for the reasons of record and reiterated herein; the claimed "enhanced LM609 antibody" can have contrasting properties and still be considered enhanced with respect to the referenced LM609 antibody. Further, the terms are not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention

Applicant's arguments are not found persuasive.

For examination purposes and as applicant acknowledges; it appears that all that is required of the "enhanced" LM609 antibody is that the activity of the enhanced LM609 grafted antibody is maintained.

B) For examination purposes the LM609 antibody is the same LM609 deposited as ATCC HB9537, as disclosed and claimed in U.S. Patent No. 5,753,230.

C) Claims 105-106 lack antecedent basis for the recitation of "enhanced LM609 grafted antibody".

D) The amendments must be supported by the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

9. Claims 56-59, 62, 65-68, 70-75, 77 are rejected under 35 U.S.C. § 102(e) as being anticipated by Brooks et al. (U.S. Patent No. 5,753,230; 1449) for the reasons of record set forth in Paper Nos. 16 / 21 / 26.

Applicant's arguments, filed 10/15/01 (Paper No. 24), have been fully considered but are not found convincing essentially for the reasons set forth previously in Paper Nos. 16 / 21 /26.

Applicant's arguments and the examiner's rebuttal are essentially the same of record.

Applicant submits that the instant enhanced antibodies are novel over the antibodies of Brooks et al. ; since that Brooks et al. does not teach an enhanced LM609 grafted antibody comprising one or more CDRs having a least one amino acid substitution in one or more CDRs of a LM609 grafted heavy chain variable region polypeptide, including SEQ ID NOS: 6 and 8.

As pointed out; for examination purposes and as applicant acknowledges; it appears that all that is required of the "enhanced" LM609 antibody is that the activity of the enhanced LM609 grafted antibody is maintained.

Therefore, the claimed "enhanced LM609 antibody" can have contrasting properties and still be considered enhanced with respect to the referenced LM609 antibody.

Given the prior art teaching of humanized LM609 antibodies and that the claimed recitation of "enhanced LM609 antibody" encompasses a variety of modified forms of the LM609, provided it differs from the native LM609 antibody; the prior art humanized antibodies read on the claimed antibodies.

Brooks et al. teach that antibodies having identical, or functionally equivalent amino acid residues sequences in their CDR regions have the same binding specificity (see Monoclonal Antibodies on columns 15-18, including column 17, paragraph 5) and teach methods for identifying antagonists of αvβ3 (see Methods for Identifying Antagonists of αvβ3 on column 18).

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The prior art and the instant claims rely upon the same LM609 antibody.

The claimed functional limitations would be inherent properties of the referenced LM609 antibodies and humanized antibodies thereof.

Applicant's arguments are not found persuasive and the rejection is maintained.

10. Claims 56-59, 62, 66-68, 70, 71, 74-76, are rejected under 35 U.S.C. § 103(a) as being unpatentable over Brooks et al. (U.S. Patent No. 5,753,230; 1449) in view of art known gene cloning and expression strategies for deriving recombinant antibodies and fragments thereof, as disclosed on pages 10-39 or Examples I and II of the instant specification or as cited by references on the 1449, including Queen et al. (5,585,089), Rosok et al. (J. Biol. Chem. 271: 22611-2618, 1996), Glaser et al. J. Immunol. 149: 3903-3913, 1992) for the reasons set forth previously in Paper Nos. 16 / 21 / 26.

Applicant's arguments, filed 10/15/01 (Paper No. 24), have been fully considered but are not found convincing essentially for the reasons set forth previously in Paper Nos. 16 / 21 /26.

Applicant's arguments and the examiner's rebuttal are essentially the same of record.

Applicant submits that the instant enhanced antibodies are nonobvious over the antibodies of Brooks et al. alone or in combination of art known gene cloning and expression strategies for deriving recombinant antibodies and fragments thereof ; since that Brooks et al. does not teach an enhanced LM609 grafted antibody comprising one or more CDRs having a least one amino acid substitution in one or more CDRs of a LM609 grafted heavy chain variable region polypeptide, including SEQ ID NOS: 6 and 8.

Applicant asserts that any known art for gene cloning and expression strategies does not cure the deficiencies of Brooks et al.

As pointed out; for examination purposes and as applicant acknowledges; it appears that all that is required of the "enhanced" LM609 antibody is that the activity of the enhanced LM609 grafted antibody is maintained.

Therefore, the claimed "enhanced LM609 antibody" can have contrasting properties and still be considered enhanced with respect to the referenced LM609 antibody.

Given the prior art teaching of humanized LM609 antibodies and that the claimed recitation of "enhanced LM609 antibody" encompasses a variety of modified forms of the LM609, provided it differs from the native LM609 antibody; the prior art humanized LM609 antibodies in combination of art known gene cloning and expression strategies for deriving recombinant antibodies and fragments thereof

read on the claimed antibodies.

Brooks et al. teach that antibodies having identical, or functionally equivalent amino acid residues sequences in their CDR regions have the same binding specificity (see Monoclonal Antibodies on columns 15-18, including column 17, paragraph 5) and teach methods for identifying antagonists of αvβ3 (see Methods for Identifying Antagonists of αvβ3 on column 18).

As pointed out previously, with respect to specific amino acid changes including those which are encompassed by "enhanced LM609"; it would have been obvious given the teachings of humanized LM609 antibodies and art known methods to generate such humanized antibodies which retain the desired functional characteristics of the native antibody and to alter said antibody for therapeutic uses, including human therapy, as taught and known in the prior art.

Therefore the primary reference clearly teaches αvβ3-specific antibodies the instant LM609 specificity and associated properties as valuable diagnostic and therapeutic tools in various biological processes. These references differ from the instant claims by not disclosing the generation of recombinant forms and nucleic acids of the LM609 antibody and hybridoma per se.

Given the availability of the LM609 antibody and hybridoma together with general immunoglobulin gene cloning and expression strategies, it would have been have been a matter of routine experimentation well within the ordinary skill level of art to generate chimeric or humanized LM609 antibodies, DNA encoding said antibodies. Given the highly conserved nature of immunoglobulin gene organization and structure and the availability of probes and PCR primers for immunoglobulin gene cloning, one of ordinary skill in the art could have isolated the functionally rearranged heavy and light chain variable regions from the LM609 hybridoma cell line and determined their sequences with a complete expectation of success. For example, the ordinary artisan does not need to determine the amino acid sequences of a rearranged V (variable) region before cloning.

The claims do not differ unexpectedly or unobviously from what one of ordinary skill in the art would have expected to obtain given the known LM609 hybridoma thereof, the known heavy and light chain and the art known techniques regarding the production of chimeric antibodies, as acknowledged by the number of available art known procedures disclosed in the instant specification and cited on the Information Disclosure Statement. For example. Queen et al. teaches the art known method of producing humanized antibodies of interest at the time the invention was made. Also, Rosok et al. and Glaser et al. teach providing for the selecting recombinant antibodies of interest, including selecting for alterations of antibody affinity.

Immunoglobulin gene structure and organization were well understood in the art a the time the claimed invention was made and that strategies for cloning the DNAs encoding immunoglobulin variable regions genes were well established in the art at the time the claimed invention was made, as were methods for the production of DNA constructs encoding immunoglobulin variable regions. In addition, it was known at the time the invention was made that the benefits of producing recombinant antibodies to reduce the immunogenicity of therapeutic and diagnostic antibodies in human patients. Also, the ordinary artisan would have selected for modified recombinant forms of the art known LM609, including those with modifications that would have provided for either lower immunogenicity or altered affinity to enhanced the diagnostic/therapeutic potential of the LM609 antibody specificity with an expectation of success at the time the invention was made. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Given the breadth of the claims to read on the LM609 antibody, the instant antibodies and nucleic acids read on a genus of antibodies (and nucleic acids) encompassed by LM609 and modifications thereof.

Applicant's arguments are not found persuasive and the rejection is maintained.

11. Claims 56-59, 62, 65-68, 70-77 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over (pending) claims 1-18 and 26-31 of copending application USSN 08/790,540 and (pending) claims 1-8, 15-26, 33-42 of copending USSN 08/791,391.

Although the conflicting claims are not identical, they are not patentably distinct from each other because each application is drawn to the same or nearly the same LM609-specific antibodies (and nucleic acid) encoding said antibodies and modifications thereof.

The specific species recited in claims 65, 72, 73, 77, 84, 85, 90, 91, 94-97 which encompass specific amino SEQ ID NOS: 90 and 94 read as species on the genus of LM609-specific recombinant antibodies.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Given that USSN 08/791,391 appears to have the same inventive entity as the instant application, USSN 08/790,540 does not appear to have the same inventive entity; the following is noted.

Claims 56-59, 62, 65-68, 70-77 are directed to an invention not patentably distinct from claims 1-18 and 26-31 of copending application USSN 08/790,540.

Commonly assigned USSN 08/790,540, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. § 103 if the commonly assigned case qualifies as prior art under 35 U.S.C. § 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 C.F.R. § 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application. A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. § 103 based upon the commonly assigned case as a reference under 35 U.S.C. § 102(f) or (g).

Applicant's arguments, filed 10/15/01 (Paper No. 24), have been fully considered but are not found convincing essentially for the reasons set forth previously in Paper Nos. 16 / 21 /26.

Applicant's arguments and the examiner's rebuttal are essentially the same of record.

Applicant submits that the claimed enhanced LM609 grafted antibodies are patentably distinct from the claims in either of copending USSN 08/790,540 and 08,791,391, since the copending USSNs are not directed to an enhanced LM609 grafted antibody comprising one or more CDRs having at least one amino acid substitution in one or more CDRs of a LM609 grafted heavy chain variable region polypeptide.

As pointed out; for examination purposes and as applicant acknowledges; it appears that all that is required of the "enhanced" LM609 antibody is that the activity of the enhanced LM609 grafted antibody is maintained.

Therefore, the claimed "enhanced LM609 antibody" can have contrasting properties and still be considered enhanced with respect to the referenced LM609 antibody.

Therefore, the claimed recitation of "enhanced LM609 antibody" encompasses a variety of modified forms of the LM609, provided it differs from the native LM609 antibody and is held obvious over the copending claims drawn to humanized LM609 antibodies

Applicant's arguments are not found persuasive and the rejection is maintained.

12. Claims 56-128 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over pending claims of copending application USSN 09/ 339,922.

Although the conflicting claims are not identical, they are not patentably distinct from each other because each application is drawn to the same or nearly the same LM609-specific antibodies (and nucleic acid) encoding said antibodies and modifications thereof.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 56-128 are directed to an invention not patentably distinct from claims 1-18 and 26-31 of copending application USSN 09/ 339,922..

Commonly assigned USSN 09/339,922, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. § 103 if the commonly assigned case qualifies as prior art under 35 U.S.C. § 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 C.F.R. § 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application. A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. § 103 based upon the commonly assigned case as a reference under 35 U.S.C. § 102(f) or (g).

Applicant's arguments, filed 10/15/01 (Paper No. 24), have been fully considered but are not found convincing essentially for the reasons set forth previously in Paper Nos. 16 / 21 /26.

13. No claim is allowed.

As indicated previously, SEQ ID NOS: 6, 8, 48, 50, 52, 54, 56, 58, 60, 62, 64, 66, 68, 70, 72, 74, 76, 78, 80, 82, 84, 86, 88, 90, 92, 94, 96, 98 and 100 appear to be free of the prior art.

Applicant is invited to limit the claims to αvβ3-specific antibodies which comprise these specific SEQ ID NOS, along with the appropriate structural and functional limitations.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel

Phillip Gambel, PhD.
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June 17, 2002